Medicare Appeals

CMS has a defined process for appeals of both Original Medicare and Part D coverage decisions. Both follow a similar 5-level structure, with specific deadlines and time limits for standard and expedited requests. This brochure is for informational purposes only and is not intended to provide reimbursement or legal advice. Information sourced as of November 2023. Please confirm information as needed.

IMPORTANT: Healthcare providers are responsible for keeping current and complying with all applicable coverage requirements and for the selection of diagnosis and procedure codes that accurately reflect their patient's condition and the services rendered. Healthcare providers also are responsible for the accuracy of all claims and related documentation submitted for reimbursement. Additional insurance requirements may apply and healthcare providers should always contact the insurer directly to obtain complete and current information. Alkermes does not guarantee coverage or reimbursement. Under no circumstances will Alkermes, Inc., or its affiliates, employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or other damages that may arise from, or be incurred in connection with, the information provided here or any use thereof.

Medicare Part D Prescription Drug Coverage Determination and Appeals Process[1-5]

Coverage Determination (Initial)	• Request submitted to patient's PDP or MA-PD • Standard: 72-hour time limit*/14-day time limit (payment) • Expedited: 24-hour time limit* *The adjudication timeframes generally begin when the request is received by the plan sponsor. However, if the request involves an exception request, the adjudication timeframe begins when the plan sponsor receives the physician's supporting statement.
LEVEL 1: Plan Redetermination	• If the plan denies the Coverage Determination, the patient or provider has 60 days to file Level 1 appeal from the date of the coverage determination notice • Appeal request submitted to PDP or MA-PD • Standard: 7-day time limit for benefits; 14-day time limit for payments • Expedited: 72-hour time limit

(continued)

Medicare Part D Prescription Drug Coverage Determination and Appeals Process (cont'd)[1-5]

LEVEL 2: Reconsideration by Part D Independent Review Entity (IRE)	• Patient or provider has 60 calendar days** to file from the date of the plan sponsor's redetermination notice • IREs are commonly called Part D Qualified Independent Contractors (QIC). Currently, C2C Innovation Solutions, Inc. is the Part D IRE • The Part D C2C Appeal form can be found at: **https://partdappeals.c2cinc.com/Prescribers/Forms** • Standard: 7-day time limit for benefits; 14-day time limit for payments • Expedited: 72-hour time limit **If, on redetermination, a plan sponsor upholds an at-risk determination made per 42 CFR § 423.153 (f), the plan sponsor must auto-forward the case to the Part D IRE within 24 hours.
LEVEL 3: Decision by the Office of Medicare Hearings and Appeals (OMHA)	• Patient or provider has 60 days to file after receipt of denial of Level 2 appeal • This level of appeal requires an "amount in controversy" (AIC) of $180.00 or more • An ALJ hearing is usually held by telephone or video-teleconference or, in some cases, in person if the ALJ finds that there is a good reason. The patient or provider may request a decision without a hearing, in which case the decision is based only on the information in the appeal record • Standard: 90-day time limit • Expedited: 10-day time limit
LEVEL 4: Medicare Appeals Council Hearing	• Patient or provider has 60 days to file after receipt of denial of Level 3 appeal • Standard: 90-day time limit • Expedited: 10-day time limit
LEVEL 5: Judicial Review – Federal District Court	• Patient or provider has 60 days to file after receipt of denial of Level 4 appeal • AIC must meet a minimum cost threshold requirement, which is adjusted annually and can be found on the CMS website • The calendar year 2023 AIC threshold amount for judicial review is $1,850

Information sourced as of November 2023. Please confirm information as needed.

Part D Drug Coverage Appeals for Redetermination[3,4]

CMS has defined a 5-level process for prescription drug coverage appeals, with specific deadlines and procedures for each level. The following information pertains to Level 1 appeal requests.

Plans are required to accept any written request for a redetermination of coverage from patients, appointed representatives, the patient's physician or other prescriber, or staff of a physician's office acting on the physician's behalf. An appeal should include:

- **Proof of representation if the prescriber or staff of the physician's office is acting on the physician's behalf as the patient's appointed representative in the appeal process. Plans cannot require additional items in request**
- The patient's name
- Information identifying which denial is being appealed
- Contact information for patient or his/her representative making the appeal
- General statement requesting an appeal; no specific wording is required

For more information about Part D drug coverage appeals, consult the Medicare Prescription Drug Benefit Manual, Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. This is available for download at: **https://www.cms.gov/Medicare/Appeals-Grievances/Prescription-Drug/Forms**

Medicare Part D Exception Process[3,6]

An exception request may include a request for benefits, a request for payment, or both. The following categories of coverage decisions may be considered for exception requests:

- **A formulary exception** is a request to obtain a Part D drug that is not included on a plan sponsor's formulary, or a request to waive utilization management restrictions for a formulary drug, e.g., step therapy, prior authorization, or quantity limits
- **A tiering exception** is a request to obtain a non-preferred drug with the cost-sharing terms of a preferred tier

Exception requests are granted when a plan sponsor determines that a requested drug is medically necessary for an enrollee. Supporting documentation will be required for the subscriber to submit an exception request.

- **For formulary exceptions,** the prescriber's supporting statement must indicate the requested non-formulary drug is medically necessary for one of three reasons:
  - All covered Part D drugs on the plan's formulary would not be effective, or may have adverse effects
  - The number of doses under a dose restriction has been or is likely to be less effective
  - The alternative(s) listed on the formulary or required to be used in accordance with step therapy are likely to be less effective or have adverse effects
- **For tiering exceptions,** the prescriber's supporting statement must indicate that the preferred drug(s) would not be as effective as the requested drug for treating the enrollee's condition, the preferred drug(s) would have adverse effects for the enrollee, or both

How to Submit a Supporting Statement[6]

The prescriber may submit their supporting statement to the plan sponsor verbally or in writing.

If submitted verbally, the plan sponsor may require the prescriber to follow up in writing:

- The Model Coverage Determination Request Form found on the CMS website in the "Downloads" section on the web page (or in the link below), or;
- An exceptions request form developed by the patient's Medicare Advantage or Part D plan sponsor or other entity, or;
- Any other written document (e.g., a letter) prepared by the prescriber

A prescriber may submit a supporting statement using the Model Coverage Determination Request form found in the "Downloads" section of the following page on the CMS website: https://www.cms.gov/Medicare/Appeals-Grievances/Prescription-Drug/Forms

How a Plan Sponsor Processes an Exception Request[6]

- Plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision within 24 hours after receiving the documentation from the prescriber (for expedited requests) or no later than 72 hours (for standard requests)
- The initial notice may be provided verbally so long as a written follow-up notice is mailed to the enrollee within 3 calendar days of the verbal notification

For requests for payment that involve exceptions, a plan sponsor must provide notice of its decision within 14 calendar days after receiving a request.

If the plan sponsor's coverage determination is unfavorable, the decision will contain the information needed to file a request for redetermination with the plan sponsor.

For more information, please consult **https://www.cms.gov/Medicare/Appeals-Grievances/Prescription-Drug/Coverage-Determinations**

References:

1. Centers for Medicare and Medicaid Services. Medicare Prescription Drug (Part D) Coverage Determination and Appeals Process. Accessed November 1, 2023. https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Flowchart-Medicare-Part-D.pdf
2. Centers for Medicare and Medicaid Services. Reconsiderations by the Independent Review Entity. Accessed November 1, 2023. https://www.cms.gov/medicare/appeals-grievances/prescription-drug/reconsiderations
3. Centers for Medicare and Medicaid Services. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. Accessed November 1, 2023. https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf
4. Medicare.gov. Medicare Appeals Booklet. Accessed November 1, 2023. https://www.medicare.gov/Pubs/pdf/11525-Medicare-Appeals.pdf
5. Federal Register. Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2023. Accessed November 1, 2023. https://www.federalregister.gov/documents/2022/09/30/2022-21284/medicare-program-medicare-appeals-adjustment-to-the-amount-in-controversy-threshold-amounts-for
6. Centers for Medicare and Medicaid Services. Exceptions. Accessed November 1, 2023. https://www.cms.gov/Medicare/Appeals-Grievances/Prescription-Drug/Exceptions